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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,375	01/31/2001	John F. McEntee	10004032-1	7821

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AGILENT TECHNOLOGIES
Legal Department, 51U-PD
Intellectual Property Administration
P.O. Box 58043
Santa Clara, CA 95052-8043

EXAMINER	
QUAN, ELIZABETH S	
ART UNIT	**PAPER NUMBER**
1743	8

DATE MAILED: 06/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/775,375	MCENTEE ET AL.	
	Examin r	Art Unit	
	Elizabeth Quan	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) 23-31 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-22 is/are rejected.

7)☒ Claim(s) 1,11,15 and 16 is/are objected to.

8)☒ Claim(s) 1-31 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 31 January 2001 is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-22, in Paper No. 6 is acknowledged. The traversal is on the ground(s) that Applicant's representative believes that all four groups of claims into which the Examiner has partitioned the original claims are intimately related to the microarray strip and features and characteristics of the microarray strip, claimed in Group I, claims 1-22. Applicant's representative cites that if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits even though it includes claims to independent or distinct inventions. Applicant's representative also points to a potential error in section 4 of the restriction requirement. Applicant's representative states that the microarray strip is directly and specifically recited in claims of each such that the serches for each of Groups I-IV would greatly overlap with one another and examination of all claims together would produce significantly less overall burden on the Examiner and provide a far more efficient and expedient examination. This is not found persuasive because Examiner has satisfied both criteria of a proper restriction by demonstrating distinctness of the groups and serious burden. Examiner has demonstrated serious burden by showing the separate classification status of the groups in the mailed restriction requirement. It is noted Examiner only deals with a portion of class 422, and the rest of the groups would be transferred to a different art unit. Furthermore, each subject of each group is considered separate subject for inventive effort, and a different field is required for each group, as recording, shipping, and scanning is not part of class 422. In regard to section 4 of the restriction requirement, Examiner made a mistake. Examiner meant to type: In the instant case the process

for using the product as claimed can be practiced by another materially different product such as a microscope slide or microtiter plate. The product as claimed can be used in a materially different process of using that product, such as performing and analyzing assays. The product does not recite the steps of the process for using, such as scanning each microarray through the transparent pocket strip.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the regularly spaced features or molded features must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because the drawings do not show the microarray strip within a second pocket tape as claimed in claim 22. It appears to show a single pocket within a second pocket tape when microarray has been defined by the independent claim as a pocket strip with a series of pockets. It the microarray strip is packaged within the second pocket tape then multiple pockets would be contained in the second pocket tape. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

5. Claim 1 is objected to because of the following informalities: In line 3 there is a misspelling: "mircoarray" should be "microarray." Appropriate correction is required.

6. Claim 11 is objected to because of the following informalities: In line 2 "and" between "via" and "adhesive" should be "an". Appropriate correction is required.

7. Claims 15 and 16 are objected to because of the following informalities: In the first lines of each claim "of" between "following" and "insertion" should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9. Claims 3, 5-10, 12-14, 19, 21, and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Referring to claims 5-10, 12, 14, 19, and 21, it is unclear whether the features in these claims are actually the same element but simply attributed to additional functionality in different claims, such as facilitating automatic translation and positioning of the microarray strip, capability of detection by optical scanning, enabling engagement with complementary features of

a mechanical translation and positioning mechanism, etc. Additionally, it is unclear what these features are.

11. Claim 13 recites the limitation "sealed chambers" in first and second lines. There is insufficient antecedent basis for this limitation in the claim.

12. In claim 16, line 3, "microarray" should be --pocket--.

13. Claim 17 recites the limitation "the well" in second line. There is insufficient antecedent basis for this limitation in the claim. Claim 16 recites a "well," but claim 17 is dependent on claim 15.

14. Referring to claims 19-22, these method claims are dependent on apparatus claims. It appears that there might have been a typo; and therefore, the claims have been treated as dependent on method claim 18 rather than apparatus claim 17.

15. Claim 21 is objected to because of the following informalities: "array" between "strip" and "for positioning" in the second line should be deleted. Appropriate correction is required.

16. Referring to claim 22, it is unclear what is exactly being claimed. Packaging the microarray strip, which has been defined with multiple pockets, within a second pocket tape would result in multiple pockets within a single second pocket tape. However, the FIG. 6 appears to show a single pocket of the microarray strip within a single second pocket tape. Does the claim intend to recite the microarray strip within a single second pocket tape or each pocket of the microarray strip packaged within individual second pocket tape?

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-5, 7-16, 18, 19, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 04-009666 to Hirokazu et al.

Referring to claims 1, 2, 13, 18, Hirokazu et al. disclose a microarray strip containing a number of microarrays (a) (see ABSTRACTS; FIGS. 1 and 2). The microarray strip comprises a pocket strip (c) with a number of pockets each containing a microarray (a) (see ABSTRACTS; FIGS. 1 and 2). A cover strip (b) is thermocompression bonded to the pocket strip (c) on three sides to create enclosed chambers from the pockets with the unbonded one side forming an aperture (d) (see ABSTRACTS; FIGS. 1 and 2). After each of the microarrays (a) are inserted into respective enclosed chambers through respective apertures (d), the inside of each of the enclosed chamber is evacuated to attain a vacuum, and the apertures (d) are heat sealed (e) to maintain the vacuum (see ABSTRACTS; FIGS. 1 and 2). Since the enclosed chamber is formed by thermocompression bonding of the cover strip (b) and pocket strip (c) on three sides, evacuating the bonded the interior of the bonded cover strip (b) and pocket strip (c), and heat sealing the aperture (d) to maintain the vacuum state and prevent other gaseous leakage, the enclosed chamber prevents exchange of liquid and vapor phase substances between the interior of the sealed chamber and external environment (see ABSTRACTS; FIGS. 1 and 2). It is noted that Applicant has distinguished the enclosed chamber from the pocket by characterizing the enclosed chamber as the pocket with the cover strip bonded to it. For examining purposes, an

enclosed chamber comprises a pocket and cover strip, such that if the enclosed chamber contains the microarray, the pocket contains the microarray.

Referring to claims 3, 4, "polymer/metal foil laminate" has been interpreted as a laminate that could be made from polymer or metal or both in light of the specification. On page 6, lines 21-31 to page 7, lines 1-4 of the immediate specification cites laminates made of a single or multiple layer(s) of plastic. Therefore, Examiner has interpreted that polymer/metal foil laminate to mean either a polymer or metal or both. In the latter interpretation Hirokazu et al. disclose that the pocket strip (c) is made from the same material as the cover strip (b), and these materials may be polyethylene, nylon, or aluminum coated films (see ABSTRACTS).

Referring to claims 5, 7-10, 19, Hirokazu et al. disclose regularly spaced features that form the walls or partitions between the enclosed chambers or pockets. These regularly spaced features are provided with stitches. These features could facilitate automatic translation and positioning of the microarray strip, comprise of or be characterized as optical features than can be detected by optical scanning, engage with complementary features of a mechanical translation and positioning mechanism, comprise of or be characterized as electromechanical features than can be detected by sensors within an electromechanical translation and positioning mechanism, comprise of or be characterized as features that can be detected by sensors to direct an electromechanical translating and positioning mechanism to translate and position the microarray strip, etc. Note that the claim language attributes the potential or capability of

the features to perform the function of facilitating automatic translation and positioning of the microarray strip, etc.

Referring to claims 5, 7-10, it is also noted that method limitations are accorded no patentable weight in apparatus claims. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. An apparatus claim covers what a device is, not what a device does (see MPEP 2114). In this case whether the features could facilitate automatic translation and position of the microarray strip, engage with complementary features of a mechanical translation and positioning mechanism, and/or can be detected by sensors has no patentable weight in the apparatus since the prior art teach the regularly spaced features which has the potential of such functionality.

Claim 11, which recites the limitation of bonding the cover strip to the pocket strip via adhesive sealant, has been construed as a product-by-process claim (see MPEP 2113). A product-by-process claim is limited by and defined by the process. Patentability is based on the product and does not depend on its method of production. If the product in the product-by-process claim is the same or obvious over a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In this case patentability of the invention is based on the product microarray strip and does not depend on its method of production. Since the microarray strip is the same as that of the prior art, the claim is unpatentable even through the prior

art uses thermocompression bonding or heat sealing rather than bonding via adhesive sealant.

Referring to claim 12, Hirozaku et al. disclose that the cover strip (b) is thermocompression bonded to the pocket strip (c) in which pressure or mechanical force and heat are applied to both the cover strip (b) and pocket strip (c) (see ABSTRACTS; FIGS. 1 and 2). Claim 12, which recites the limitation of the cover strip (b) being bonded to the pocket strip (c) via mechanical force applied to complementary molded features of the pocket strip (c) and cover strip (b), has been construed as a product-by-process claim (see MPEP 2113). A product-by-process claim is limited by and defined by the process. Patentability is based on the product and does not depend on its method of production. If the product in the product-by-process claim is the same or obvious over a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In this case patentability is based on the product microarray strip and does not depend on its method of production. It does not matter whether the cover strip is bonded to the pocket strip via mechanical force or complementary features of the pocket strip and cover strip is molded as long as the prior art has the cover strip and pocket strip.

Referring to claim 14, Hirokazu et al. disclose each pocket inherently with structural features for positioning and orienting a microarray within the pocket. Claim 14, which recites the limitation of each pocket with molded features for positioning and orienting a microarray within the pocket, has been construed as a product-by-process claim (see MPEP 2113). A product-by-process claim is limited by and defined by the process. Patentability is based on the product and does not depend on its method of

production. If the product in the product-by-process claim is the same or obvious over a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In this case patentability is based on the product microarray strip and does not depend on its method of production. It does not matter whether or not the pocket has features that are molded as long as the prior art has the feature.

Referring to claim 15, Hirokazu et al. disclose a gap between the upper surface of the microarray (a) and inner surface of the cover strip (b) that may be filled by an adhesive, such as a pressure sensitive film or adhesive tape (see ABSTRACTS). According to Merriam-Webster Collegiate Dictionary, a gap is defined as a break in continuity. Therefore, the adhesive breaks the continuity between the upper surface of the microarray (a) and inner surface of the cover strip (b).

Referring to claim 16, Examiner has interpreted the gaps in two ways: gaps between the surfaces of the microarray and the bottom and side surfaces of the pocket and wells labeled as "gaps." Hirokazu et al. disclose gaps between the surfaces of the microarray and side surfaces of the pocket. Hirokazu et al. do not explicitly disclose gaps between the surfaces of the microarray and bottom surfaces of the pocket. However, gaps are inherent between any two surfaces as two surfaces are inherently imperfect and would inherently fit together imperfectly to create such discontinuities or gaps. Hirokazu et al. also disclose gaps on the surface of the microarray creating wells into which solutions can be introduced. It is also noted that method limitations are accorded no patentable weight in apparatus claims. A recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus

from a prior art apparatus if the prior art apparatus teaches all the structural limitations of the claim. An apparatus claim covers what a device is, not what a device does (see MPEP 2114). In this case it does not matter if the gaps create a well into which solutions can be introduced since the prior art teaches all the structural limitations of the claim, including the gaps.

Referring to claim 21, Hirokazu et al. disclose the pockets of the microarray strip with support features or supporting shape for positioning and orienting microarrays within the pockets. Note that the claim language attributes the potential or capability of the feature to position and orient microarrays within the pockets.

Therefore, Hirokazu et al. include all the limitations in claims 1-5, 7-16, 18, 19, 21.

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 04-009666 to Hirokazu et al. in view of U.S. Patent No. 3,700,089 to Halbartschlager et al. or U.S. Patent No. 5,101,975 to Runyon et al. or U.S. Patent No. 5,880,829 to Kauhaniemi et al.

Referring to claim 6, Hirokazu et al. do not disclose that the regularly spaced features comprise of two sets of tractor feed perforations along each edge of the microarray strip. It is very well known to have two sets of tractor feed perforations along each edge of the microarray strip. Runyon et al. show two sets of tractor feed perforations along each edge of the microarray strip. Halbartschlager et al. disclose two sets of tractor feed perforations along each edge of the microarray strip to aid in transporting the strip (see COL. 3, lines 11-17 and 61-67; COL. 4, lines 1-20). Kauhaniemi et al. disclose two sets of tractor feed perforations along each edge of the microarray strip also to aid in transporting the strip (see FIG. 3; COL. 3, lines 1-10 and 25-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microarray strip of Hirokazu et al. to provide two sets of tractor feed perforations along each edge of the microarray strip as in

Halbarschlager et al. or Runyon et al. or Kauhaniemi et al. to aid in dispensing or transporting the microarray strip as it is very well known and adapts to existing automation.

23. Claims 17 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 04-009666 to Hirokazu et al. in view of U.S. Patent No. 3,924,746 to Haines.

Referring to claims 17 and 20, Hirokazu et al. do not disclose one or more septa affixed to a surface of the cover strip. According to Merriam Webster Collegiate Dictionary, septa or septum are/is defined as a dividing wall or membrane especially between bodily spaces or masses of soft tissue. Haines disclose septa (30,32) affixed to a surface of the cover strip (26) (see FIG. 2; COL. 1, lines 32-49; COL. 2, lines 15-51). The laminate of the septa (30,32) and cover strip (26) may be peeled or resealed to reveal or close a port through which solutions and gases can be introduced into or extracted from the well of the microarray in the pocket (see FIG. 2). The laminate has a high resistance to tearing or tampering to prevent accidental opening or unsealing of the laminate from the pocket (see ABSTRACT; COL. 1, lines 32-49; COL. 2, lines 15-51). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microarray strip of Hirokazu et al. to provide one or more septa affixed to a surface of the cover strip as in Haines to provide high resistance to tearing or tampering to prevent accidental opening or unsealing of the laminate from the pocket.

24. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 04-009666 to Hirokazu et al. in view of U.S. Patent No. 4,434,893 to Barlow and/or U.S. Patent No. 4,169,531 to Wood.

Referring to claim 22, Hirokazu et al. do not disclose packaging the microarray strip within a second pocket tape. Barlow shows a pocket (23) of the microarray strip packaged within a second pocket tape (25) to further protect the contents of the pocket of the microarray strip as well as the pocket of the microarray strip (see FIG. 2). The construction provide a gas tight environment within the pockets and tamper evident packaging, which is important to avoid accidental reuse or contamination or at least provide an indication of contents has been disturbed during detection or analysis of contents. Wood shows multiple pockets (21) packaged within a single second pocket tape (22) (see FIG. 3). The construction provides for individual packaging of arrays and protection from the environment and light as well as accidental opening of the pockets (see ABSTRACT; FIG. 3; COL. 1, lines 31-50). The package, which is both convenient and useful, may be manufactured economically (see COL. 1, lines 47-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the microarray strip of Hirokazu et al. to package the microarray strip within a second pocket tap as in Barlow and/or Wood to provide an economical, convenient, and useful tamper evident package that is gas tight and light tight.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. They include one or more limitations in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Quan whose telephone number is (703) 305-1947. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Elizabeth Quan
Examiner
Art Unit 1743

eq
June 2, 2003

Jill Warden
Supervisory Patent Examiner
Technology Center 1700